

Renée E. Rothauge, OSB #903712
ReneeRothauge@markowitzherbold.com
Lauren F. Blaesing, OSB #113305
LaurenBlaesing@MarkowitzHerbold.com
MARKOWITZ HERBOLD PC
Suite 3000, Pacwest Center
1211 SW Fifth Avenue
Portland, OR 97204-3730
Telephone: (503) 295-3085
Fax: (503) 323-9105

Bryan Pratt (*admitted pro hac vice*)
bpratt@shb.com
Laura Lawson (*admitted pro hac vice*)
llawson@shb.com
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108
Telephone: (816) 474-6550
Fax: (816) 421-5547

*Attorneys for Defendants Medtronic USA,
Inc., Covidien Holding, Inc., and
Covidien Sales, LLC*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON
PORTLAND DIVISION

LAURA SNYDER,

Case No.: 3:18-cv-00332-YY

Plaintiff,

vs.

**DEFENDANTS MEDTRONIC USA,
INC., COVIDIEN HOLDING, INC., AND
COVIDIEN SALES, LLC'S ANSWER
TO PLAINTIFF'S COMPLAINT AND
AFFIRMATIVE DEFENSES**

KAISER FOUNDATION HOSPITALS, a
California corporation, MEDTRONIC USA,
INC., an active Minnesota corporation,
PHILIPS NORTH AMERICA, LLC, an
active foreign limited liability company,
COVIDIEN HOLDING, INC. formerly
known as COVIDIEN, INC., an active
foreign limited liability company,
COVIDIEN SALES, LLC, an active foreign
limited liability company, and COFFEY
MEDICAL, INC., an active Indiana
corporation,

Defendants.

Defendants Medtronic, Inc., incorrectly denominated as Medtronic USA, Inc., Covidien Holding, Inc., and Covidien Sales, LLC (collectively, “Medtronic”), for their Answer and Affirmative Defenses to Plaintiff’s Complaint, state as follows:

1.

Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 of Plaintiff’s Complaint and therefore denies the same.

2.

Medtronic admits that Medtronic, Inc. is a Minnesota corporation with its principal place of business in Minnesota, and is authorized to do business in Oregon. Medtronic admits it is in the business of making medical products, including the manufacturing of electrodes and leads. Medtronic denies all other allegations contained in Paragraph 2 of Plaintiff’s Complaint.

3.

Medtronic admits that Covidien Holding, Inc. is a Delaware corporation with its principal place of business in Massachusetts, and is authorized to do business in Oregon. Medtronic admits it is in the business of making medical products, including the manufacturing of electrodes. Medtronic denies all other allegations contained in Paragraph 3 of Plaintiff’s Complaint.

4.

Medtronic admits that Covidien Sales, LLC is a Delaware limited liability company with its principal place of business in Massachusetts, and is authorized to do business in Oregon. Medtronic admits it is in the business of making medical products, including the manufacturing of electrodes. Medtronic denies all other allegations contained in Paragraph 4 of Plaintiff’s Complaint.

5.

Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 5 of Plaintiff's Complaint and therefore denies the same.

6.

Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 6 of Plaintiff's Complaint and therefore denies the same.

7.

Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 7 of Plaintiff's Complaint and therefore denies the same.

8.

Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 8 of Plaintiff's Complaint and therefore denies the same.

9.

Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 9 of Plaintiff's Complaint and therefore denies the same.

10.

The allegations set forth in Paragraph 10 of Plaintiff's Complaint call for a legal conclusion and no response is required. To the extent a response is required and is directed to Medtronic, Medtronic denies the allegations contained in Paragraph 10 of Plaintiff's Complaint. To the extent Paragraph 10 of Plaintiff's Complaint is directed to other Defendants, Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 10 of Plaintiff's Complaint and therefore denies the same.

11.

The allegations set forth in Paragraph 11 of Plaintiff's Complaint call for a legal conclusion and no response is required. To the extent a response is required and is directed to Medtronic, Medtronic denies the allegations contained in Paragraph 11 of Plaintiff's Complaint. Medtronic specifically denies that a Medtronic electrode and/or lead was "misbranded, defective, and unreasonably dangerous."

12.

Paragraph 12 of Plaintiff's Complaint is directed to Defendants other than Medtronic. The allegations set forth in Paragraph 12 of Plaintiff's Complaint call for a legal conclusion and no response is required. To the extent a response is required and is directed to Medtronic, Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 12 of Plaintiff's Complaint and therefore denies the same.

13.

The allegations set forth in Paragraph 13 of Plaintiff's Complaint call for a legal conclusion and no response is required. To the extent a response is required, Medtronic denies the allegations contained in Paragraph 13 of Plaintiff's Complaint. Medtronic specifically denies that Plaintiff is entitled to the relief sought in Paragraph 13 of Plaintiff's Complaint.

14.

Medtronic denies that Plaintiff is entitled to the relief sought in Paragraph 14 of Plaintiff's Complaint.

PRAYER FOR RELIEF

Medtronic denies that Plaintiff is entitled to the relief sought in the "WHEREFORE" paragraph following Paragraph 14 of Plaintiff's Complaint.

GENERAL DENIAL

Unless expressly admitted above, Medtronic denies each and every allegation contained in Plaintiff's Complaint.

AFFIRMATIVE DEFENSES

Medtronic asserts that Plaintiff's claims are barred, in whole or in part, by the defenses set forth below. By setting forth these defenses, Medtronic does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, nothing herein stated is intended or shall be construed as an acknowledgement that any particular issue or subject matter is relevant to Plaintiff's allegations. Medtronic reserves the right to plead any and all affirmative defenses that may become evident or appreciated after investigation and discovery in this matter.

FIRST AFFIRMATIVE DEFENSE

15.

Plaintiff's Complaint, and each cause of action therein, fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

16.

Plaintiff's claims may be barred by the applicable statute of limitations, prescription, and/or statute of repose, including but not limited to, those limitations enumerated in Or. Rev. Stat. § 30.905.

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THIRD AFFIRMATIVE DEFENSE

17.

Plaintiff's claims may be barred by the doctrines of equitable estoppel, waiver, and laches.

FOURTH AFFIRMATIVE DEFENSE

18.

Plaintiff's claims may be barred for failure to join necessary and/or indispensable parties.

FIFTH AFFIRMATIVE DEFENSE

19.

If Plaintiff was injured or damaged as alleged, no injury or damages being admitted, such injuries were not caused by a product designed, manufactured, and/or sold by Medtronic.

SIXTH AFFIRMATIVE DEFENSE

20.

There was no defect in the product described in Plaintiff's Complaint with the result that Plaintiff is not entitled to recover against Medtronic in this cause. Further, Plaintiff's claims are barred by her failure to allege a defect.

SEVENTH AFFIRMATIVE DEFENSE

21.

There was no causal connection between any alleged defect in the product described in Plaintiff's Complaint and the damages alleged in the Complaint, with the result that Plaintiff is not entitled to recover against Medtronic.

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EIGHTH AFFIRMATIVE DEFENSE

22.

Plaintiff's claims are barred because Medtronic did not owe a legal duty to Plaintiff. If Medtronic owed a legal duty to Plaintiff, Medtronic did not breach that duty.

NINTH AFFIRMATIVE DEFENSE

23.

Plaintiff's claims are barred because any alleged breach of duty, which Medtronic denies, was not a proximate cause of the injuries and damages alleged in the Complaint.

TENTH AFFIRMATIVE DEFENSE

24.

Plaintiff's claims are barred because the benefits of the product outweighed its risks.

ELEVENTH AFFIRMATIVE DEFENSE

25.

If Plaintiff has been damaged, which Medtronic denies, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Medtronic is not legally responsible.

TWELFTH AFFIRMATIVE DEFENSE

26.

If Plaintiff suffered any damages or injuries, which Medtronic denies, such damages were caused by the unforeseeable acts, wrongs, or omissions by intervening or superseding actions of third parties for which Medtronic is not responsible.

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THIRTEENTH AFFIRMATIVE DEFENSE

27.

If Plaintiff has been damaged, which Medtronic denies, the actions of persons and/or entities for whose conduct Medtronic is not legally responsible and the independent knowledge of those persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of the damages alleged in Plaintiff's Complaint.

FOURTEENTH AFFIRMATIVE DEFENSE

28.

If Plaintiff has been damaged, which Medtronic denies, the negligence or fault of Plaintiff must be compared, reducing or completely barring Plaintiff's alleged right to recover against Medtronic.

FIFTEENTH AFFIRMATIVE DEFENSE

29.

If Plaintiff has been damaged, which Medtronic denies, the negligence or fault of persons or entities, for whose conduct Medtronic is not legally responsible, must be compared, reducing or completely barring Plaintiff's alleged right to recover against Medtronic.

SIXTEENTH AFFIRMATIVE DEFENSE

30.

In the event that it is determined that Plaintiff is entitled to recover against Medtronic, recovery should be reduced in proportion to the degree or percentage of negligence, fault, or exposure to products attributable to Plaintiff, any other defendants, third-parties or other persons, including any party immune because bankruptcy renders them immune from further litigation, as

well as any party, co-defendant, or non-parties with whom Plaintiff has settled or may settle in the future, in accordance with Oregon law.

SEVENTEENTH AFFIRMATIVE DEFENSE

31.

The injuries and damages allegedly sustained by Plaintiff may be due to the operation of nature or idiosyncratic reaction(s) and/or unrelated pre-existing condition(s) in Plaintiff, over which Medtronic had no control and which were unrelated to the product at issue.

EIGHTEENTH AFFIRMATIVE DEFENSE

32.

Plaintiff, in consenting to the treatment described by her physician or other healthcare professional, expressly and voluntarily assumed the risk of injury or adverse effect associated with the device that is the subject of Plaintiff's Complaint. In consenting to the treatment described by her physician or other healthcare professional, Plaintiff is comparatively at fault by voluntarily assuming the risk of injury or adverse effect associated with the surgery and/or the device referenced in Plaintiff's Complaint.

NINETEENTH AFFIRMATIVE DEFENSE

33.

To the extent Plaintiff failed to mitigate the alleged damages, any recovery shall not include alleged damages that Plaintiff could have avoided by reasonable care and diligence.

TWENTIETH AFFIRMATIVE DEFENSE

34.

Plaintiff's recovery against Medtronic is barred to the extent the product described in Plaintiff's Complaint, if such product was designed, manufactured, and/or sold by Medtronic,

was not in the same condition at the time of the events, injuries, and damages alleged in Plaintiff's Complaint as when it left the custody and possession of Medtronic.

TWENTY-FIRST AFFIRMATIVE DEFENSE

35.

If Plaintiff has been damaged, which Medtronic denies, such damages were caused by unforeseeable misuse, abuse, abnormal use, user error, alterations, changes, and/or modifications of the product described in Plaintiff's Complaint for which Medtronic was and is in no way liable.

TWENTY-SECOND AFFIRMATIVE DEFENSE

36.

Plaintiff's claims are barred by the learned intermediary, informed intermediary, bulk supplier, and/or sophisticated user doctrines. Alternatively, Medtronic denies any liability because Plaintiff's treating physician elected to use the subject device with full knowledge of any foreseeable risk.

TWENTY-THIRD AFFIRMATIVE DEFENSE

37.

Plaintiff's claims are barred because the methods, standards, and techniques used in designing, manufacturing, marketing, distributing, and/or selling the product at issue, to the extent it was designed, manufactured, and/or sold by Medtronic, conformed with the generally recognized, reasonably available, and reliable state of knowledge when the product was manufactured and marketed. All acts of Medtronic at the time of the alleged design, manufacture, and/or sale of the product at issue were in conformity with the state-of-the-art of the medical device industry at all relevant times. Further, the methods, standards, and techniques used in designing, manufacturing, and/or marketing any Medtronic product alleged to be at issue

were in conformity with industry custom, usage, and standards and/or legislative, administrative, or regulatory standards. As such, the product in question was neither defective nor unreasonably dangerous at the time it allegedly left Medtronic's control.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

38.

Any alleged defects of the product and/or any alternative design claimed by Plaintiff were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and/or sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

39.

Alternatively, Medtronic pleads that the damages alleged, if any, were caused by an inherent characteristic of the product described in Plaintiff's Complaint, which cannot be eliminated without substantially compromising its usefulness or desirability.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

40.

The conduct of Medtronic and the subject product at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

41.

To the extent the product described in Plaintiff's Complaint was designed, manufactured, and/or sold by Medtronic, it was neither defective nor unreasonably dangerous because it is a

medical device falling within what is commonly known as Comments (j) and (k), Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of Torts (Products Liability), in that the product at issue was, at all times material to Plaintiff's Complaint, reasonably safe and reasonably fit for its intended use.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

42.

Medtronic asserts any and all defenses, claims, credits, offsets, or remedies provided by the Restatement (Second) of Torts and/or the Restatement (Third) of Torts and reserves the right to amend its Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

TWENTY-NINTH AFFIRMATIVE DEFENSE

43.

If Plaintiff recovers from Medtronic, which liability is specifically denied, Medtronic is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiff's alleged damages and/or who may have released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims.

THIRTIETH AFFIRMATIVE DEFENSE

44.

Should Medtronic be held liable to Plaintiff, which liability is specifically denied, Medtronic would be entitled to a set-off for the total of all amounts paid to Plaintiff from all collateral sources.

THIRTY-FIRST AFFIRMATIVE DEFENSE

45.

To the extent any award of pre-judgment interest is sought on future damages, such award violates the due process clause of the United States Constitution and the Oregon Constitution.

THIRTY-SECOND AFFIRMATIVE DEFENSE

46.

Medtronic pleads any applicable limitation on recovery of damages as to amount or type, including statutory caps on damages, as may be applicable to this matter under Oregon law and other applicable laws and/or regulations.

THIRTY-THIRD AFFIRMATIVE DEFENSE

47.

Medtronic incorporates any affirmative defenses asserted by other Defendants to the extent they do not conflict with Medtronic's affirmative defenses.

RESERVATION OF RIGHTS

48.

Medtronic reserves the right to assert, and hereby gives notice that it intends to rely upon, any other defense that may become available or appear during discovery proceedings or otherwise in this case and hereby reserves the right to amend its Answer to assert any such defense.

DEMAND FOR JURY TRIAL

Medtronic specifically requests and demands a trial by jury as to all issues so triable.

WHEREFORE, Medtronic prays that:

- (1) Plaintiff takes nothing by reason of her Complaint;
- (2) the Complaint be dismissed in its entirety and that a Judgment against Plaintiff and in favor of Medtronic be entered;
- (3) Medtronic be awarded its costs and expenses; and
- (4) this Court award Medtronic any other general or specific relief as this Court may deem just and proper.

DATED this 1st day of March, 2018.

MARKOWITZ HERBOLD PC

By: *s/ Lauren F. Blaesing*

Renée E. Rothauge, OSB #903712
ReneeRothauge@Markowitzherbold.com
Lauren F. Blaesing, OSB #113305
LaurenBlaesing@MarkowitzHerbold.com
-and-
SHOOK, HARDY & BACON L.L.P.
Laura B. Lawson, *admitted pro hac vice*
llawson@shb.com
Bryan T. Pratt, *admitted pro hac vice*
bpratt@shb.com

Of Attorneys for Defendants Medtronic USA,
Inc., Covidien Holding, Inc., and Covidien
Sales, LLC

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